

# Binder Free Diaphragm Pacing and Airway Clearance Assistance

Grant R43NS052993 | Period of support: 04/2006 – 10/2006

## Challenge/Problem:

Loss of respiratory muscle control in high level spinal cord injury (SCI) and the progressive decline in amyotrophic lateral sclerosis (ALS) results in the inability to maintain adequate ventilation or clear air passages of secretion. Restoration of these functions are necessary for the health, well being and quality of life of the individual.

## Progress:

We have implanted over 25 patients with the DPS System to allow SCI patients to breathe without a mechanical ventilator and condition the diaphragm of ALS patients. These patients have demonstrated the inspiratory function of the DPS System and are candidates for the addition of new function for airway clearance and binder free stimulation.

## Approach:

We have developed a minimally invasive approach to implementing a Diaphragm Pacing Stimulation (DPS) System. The DPS System consists of intramuscular electrodes, implanted in the diaphragm, during an outpatient surgical procedure. Leads are percutaneously connected to an external stimulator. This stimulator is programmed with the parameters and algorithm to provide the ventilatory support for the individual. This project will expand the stimulation (hardware and algorithms) to include expiratory muscles to assist in airway clearance and eliminate the need for an abdominal binder.

## Current/Near Term Products:

The initial product will be the NeuR<sub>x</sub> RA/4 DPS System, which is currently in human clinical trials for restoration of ventilation in spinal cord injured patients and conditioning of the diaphragm in patients with amyotrophic lateral sclerosis.

The addition of airway clearance assistance and utilization without an abdominal binder will be a second generation product.

## Business Name and Point of Contact:

Synapse Biomedical, Inc.  
300 Artino St., Oberlin OH 44074

Anthony R. Ignagni  
President & CEO

## Future Plans:

The evolution of the technology will include the incorporation of implantable pulse generator technology and expansion to additional clinical indications.

Keywords: Diaphragm, ALS, SCI, neuroprosthesis, stimulation